

Remarks

Claims 1-20 and 28-32 were pending in the application. Claims 1, 10, 15, 16, 17, 29, 30 and 31 have been amended. Claims 14 and 32 have been cancelled. Claims 33 and 34 have been added. Accordingly, claims 1-13, 15-20, 28-31 and 33-34 are currently pending in the application. The specification has been amended to include element number 35 after the word "slit". No new matter has been added by the amendments.

Bearing in mind the remarks below, the application has been amended to place it in condition for allowance. An early indication of the same would be greatly appreciated.

Support for Amended Claim 1

Claim 1 filed herewith has been amended to refer to the fact that the first tubular portion envelops the ankle and the entire circumference of a portion of the patient's lower leg. Support for this amendment may be found in lines 9 to 13 of page 6, and in Figs. 3 and 4 of Applicant's specification.

The identified paragraph of the description states that the orthosis envelops the lateral and medial malleoli (i.e. the ankle), and Figs. 3 and 4 clearly show that the orthosis does indeed extend around the entire circumference of the patient's lower leg. Furthermore, as a "sock" always extends around the entire circumference of one's leg, so the reference to a "sock" in the specification would imply to one skilled in the art that the orthosis does indeed extend, as shown in the Figures, around the entire circumference of a portion of the patient's lower leg.

It is submitted, therefore that this amendment has full support in Applicant's specification as filed.

Support for New Claims 33 and 34

New claim 33 filed herewith refer to the embodiment of the invention depicted in Fig. 3 of the drawings. As shown in that figure, the orthosis envelops the patient's lower leg, calcaneum and foot, but does not envelop the patient's toes.

Support for claim 33 which refers to the toes being enveloped may be found at page 6, lines 13-14 of Applicant's specification wherein it is stated that: "the toes 49 of the foot are not enveloped by the orthosis, *although they could be enveloped if desired*".

New claim 34 filed herewith refers to a method of manufacture which is described in detail in lines 22 to 31 of page 7 to line 2 of page 8 of Applicant's specification. Attention is specifically directed to line 19 where explicit reference is made to the fact that silicone elastomer may be manually fitted to a cast of the patient's foot.

Objection to Drawings Under 37 CFR § 1.83(a)

In the Office action mailed August 13, 2002, the drawings were objected to for failing to show an insertion slit as specified in claim 1 and elsewhere.

Enclosed herewith is a Letter to Chief Draftsperson and a copy of sheet 2 of the drawings that includes an amended Fig. 3 which shows, by means of two broken lines in red ink, an insertion slit 35.

Lines 16 and 17 of page 6 of the description clearly state that the slit extends "in a direction towards the calcaneum between the medial and lateral malleoli", and the proposed amendment to Fig. 3 is entirely consistent with this description of the slit. It is submitted, therefore, that the proposed amendment to Fig. 3 has full support in the application papers as filed.

The proposed drawing correction as required in the Office action has been submitted. Therefore the objection to the drawings should be withdrawn.

Rejection Under 35 U.S.C. § 112 - Claim 1

In the Office action dated August 13, 2002, claim 1 was rejected under 35 USC § 112 due to a lack of support for the references in the claim to "first and second tubular portions".

It is accepted that the specification does not include a verbatim recitation of the particular language used in amended claim 1, but it is nevertheless submitted that these features are in fact fully supported by the application papers as filed.

The description of the present application is clearly related to a "sock", and claim 1 as originally filed did in fact specifically refer to "a sock-like structure".

As the Examiner is no doubt aware, a sock is generally a covering that is worn on the foot and which usually extends above the ankle of the wearer. Webster's International Dictionary defines a "sock" as a "covering for the foot usually extending above the ankle and sometimes to the knee...".

As anyone who has ever purchased, or indeed worn, a sock will know, socks must have a generally tubular structure so that they can be pulled over the foot. If a sock did not have a tubular structure, then it would be impossible to pull it on to one's foot, and it would fall off the foot as it is the elastic nature of the tubular structure which retains the sock on the foot.

It is also generally well known that socks typically comprise two such tubular portions which are set at an angle to one another, that angle being designed to mimic the normal angle between the lower leg and foot of a human. A sock that did not have two portions set at an angle to one another would be more akin to a glove, and would be extremely uncomfortable to wear as the material of the sock would tend to bunch in the region of the ankle around the join between the lower leg and the foot.

It is the case, therefore, that a sock intrinsically comprises a tubular structure formed of two tubular portions. Accordingly, the amendment to claim 1 to refer to these structural features merely makes explicit that which was implicitly defined by the language of the application as originally filed.

In other words, Applicant would respectfully submit that the reference to a "sock" in the application as originally filed implicitly included all of the features of amended claim 1 which were alleged to lack support.

It is also respectfully submitted that the test for support in an application as filed should not simply comprise a "word search" in the description for wording identical to that used in the claim. Rather, the test should be whether the specification contains a written description in terms which enable any person *skilled* in the art to make and use the invention. As demonstrated above, in the present case it would not need someone skilled in the art to appreciate the particular features of a "sock" as referred to by Applicant. Rather any person, it is submitted, reading the specification would immediately appreciate the structural features that all socks possess.

Notwithstanding the above, Applicant would also point out that the drawings of the application as filed explicitly show the features now claimed.

Specifically, Fig. 3 (Sheet 2) of the drawings shows a generally L-shaped structure which includes a first portion that overlies the ankle and part of the lower leg, and a second portion which overlies the dorsal and plantar aspects of the foot.

Fig. 3 is a perspective view of the orthosis of the invention, and the shaded ellipses at either end of the orthosis clearly are the conventional means used by draftspersons to indicate that the structure shown is hollow. No doubt the Chief Draftsperson will be able to confirm that

Fig. 3 does indeed show a hollow (and hence tubular) generally L-shaped structure.

In addition, the fact that a foot is shown in dashed lines in Fig. 4 clearly indicates that the orthosis of the invention is designed to fit over the foot of a patient, and as such it must comprise a hollow tubular structure.

Applicant would also respectfully point out that lines 22 to 31 of page 7 and lines 1-2 of page 8 of the specification describe a method of manufacture where the elastomer mixture from which the orthosis is made is described as being "manually fitted to a plaster cast of the patient's foot". As the human foot and lower leg are generally cylindrical, a cast of the foot/leg would give a three-dimensional generally cylindrical body and an orthosis formed on that cast would, by definition, have a tubular structure. It would, in fact, be impossible to produce anything other than a tubular structure by means of such a method of manufacture.

Applicant would also point out that claim 1 as filed on April 30, 2002 was amended to include a recitation of the aforementioned first and second tubular structures solely because the "sock-like" language of claim 1 as originally filed was deemed to be "indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention".

The amendment of original claim 1 to refer to first and second tubular portions was a *bona fide* attempt to introduce structure into the claim to avoid this objection. The amendment made by Applicant incorporated structural features of a sock into the language of the claim, and those features - as explained above - have both explicit and implicit basis in the application papers as originally filed.

Applicant would respectfully submit, therefore, that the reference to first and second tubular portions in amended claim 1 filed herewith is fully supported by the application

papers as originally filed. The Examiner is therefore respectfully requested to withdraw the objection.

Rejection Under 35 USC § 112 - Claim 10

In the Office action dated August 13, 2002, claim 10 was also rejected under 35 USC § 112 due to a lack of support for the reference in the claim to "the stiffness of the reinforcing means being greater than that of the first and second tubular portions".

The amendment to refer in claim 10 to "stiffness" was a mistake made by Applicant. Applicant is grateful to the Examiner for picking up this error, and amended claim 10 filed herewith correctly states that the rib has a "resilience" which is greater than the resilience of the first and second tubular portions.

Support for this amendment may be found in lines 6-8 of page 6 of Applicant's specification as filed. It is respectfully submitted, therefore, that the objection previously raised against claim 10 may now be withdrawn.

Rejection Under 35 USC § 112 - Claims 29 & 32

In the Office action dated August 13, 2002, claims 29 and 32 were also rejected under 35 USC § 112 due to a lack of support for the references in the claims to "the thickness of the first and second tubular portions".

Claim 32 has been cancelled by virtue of this preliminary amendment, and claim 29 has been amended to refer to the "resilience" of the first and second tubular portions.

This amendment has full support in lines 6-8 of page 6 of the specification as filed, and Applicant would therefore respectfully submit that the objection previously raised should now be withdrawn.

Rejection Under 35 USC § 112 - Claim 31

In the Office action dated August 13, 2002, claim 31 was also rejected under 35 USC § 112 due to a lack of support for the reference in the claim to "the first flexural stiffness" and "the second flexural stiffness".

The term "flexural stiffness" was adopted by Applicant on the basis that it is a synonym of "resilience". Applicant appreciates the Examiner's concerns regarding this phrase, and as a consequence claim 31 filed herewith has been amended to refer to "resilience".

Support for this amendment may be found in lines 6-8 of page 6 of Applicant's specification as filed.

Rejection Under 35 USC § 112 - Claims 11 to 14

In the Office action dated August 13, 2002, claims 11 to 14 were rejected under 35 USC § 112 as being indefinite. The amendment proposed to Fig. 3 of the drawings corrects this deficiency, and if that amendment is allowed then this objection should, we submit, now be withdrawn.

Rejection Under 35 USC § 103

Claims 1 and 31 were rejected under 35 USC § 103(a) as being unpatentable over Hall ('324) in view of Hill ('359). Withdrawal of the rejection is hereby respectfully requested.

Applicant notes that the Office Action dated 13 August 2002 alleges, *inter alia*, that Hall discloses:

"first and second tubular portions integrally formed".

On close inspection of the Hall reference, it would appear to Applicant that this statement may not be factually correct.

Col. 4, lines 6 to 31 of Hall explain that the anterior support 10 is provided with a hook-and-loop type

fastener patch 26 (cf. velcro®), and that the "strap includes a hook-and-loop type fastener patch 24....on the interior surface of the strap" (see lines 21 to 24 of Column 4). Lines 25 to 27 of Column 4 of Hall tell us that "both ends of the strap 20 and 22 may be readily secured to the patch 26 for securing the brace to the leg 12".

It is clear, therefore, that the strap 20 which is alleged to form part of the "first tubular portion" (as recited in Applicant's claim) of the Hall device is **separable** from the support. It follows, therefore that Hall does not disclose a "first tubular portion integrally formed with a second tubular portion". In fact, it discloses the exact opposite, namely a first tubular portion (comprised of the support 10 and strap 20) which is formed as two distinct pieces, and hence which **cannot** be integrally formed with the second tubular portion.

Applicant also notes that the Office Action dated August 13, 2002 alleges, *inter alia*, that Hill discloses:

"a tubular portion formed of 35 shore silicone elastomer"

On close inspection of the Hill reference, it would appear to Applicant that this statement may also be incorrect.

Lines 2 to 5 of Column 3 of Hill state:

"In the case where a **rigid** calf band is necessary the band may be made of 40-70 durometer silicone sheeting..." (emphasis added).

It is apparent, therefore that Hill actually discloses a **rigid** calf band of 40-70 durometer silicone sheeting, not resiliently **flexible** 35 shore silicone as claimed by Applicant.

The Office action alleges that a skilled person would be motivated to combine the material taught by Hill with

the structure of the device taught by Hall to arrive at Applicant's invention.

A first point to note is that there is nothing in Hill to suggest that it is only the material disclosed for use as the calf band that is important.

A skilled person reading Hill would not be motivated to select *only* the material disclosed for the calf band, any more than they would be motivated to select *only* the material disclosed for the two flexible brace rods 5.

The invention disclosed in Hill is a combination of a number of discrete components, and there is no suggestion in Hill that any one of these components may be selected without also selecting the remaining components. All of the components disclosed in Hill are important to the invention disclosed therein.

It would appear to Applicant, that by selecting solely the material used for the calf band, the Examiner may inadvertently have used the benefit of hindsight to select only those features of relevance to Applicant's invention, all other features being discarded. This, it is submitted, is not a basis on which to make an allegation of a lack of inventive step.

If we assume, *arguendo*, that someone skilled in the art were to combine Hill and Hall, then they would actually be motivated to provide a support 10 which fitted inside a shoe (as taught by Hall - see Fig. 2 and line 38, Column 2), and additionally a pair of flexible brace rods 5 (as taught by Hill) which engaged with a plate 11 built into the heel of the shoe (see Fig. 2 of Hill for example). The inside shoe support taught by Hall and the flexible brace rods taught by Hill could both be secured to the patient's leg by means of a calf band (as taught in both Hall and Hill), and that band could be a rigid band of 40 - 70 durometer silicone sheeting as taught in Hill.

Under no circumstances would that skilled person be motivated to provide a resiliently flexible silicone structure comprised of first and second integrally formed tubular structures, as claimed by Applicant. Any suggestion that they would be motivated to provide such a device can only be arrived at with the benefit of hindsight, or in other words by means of an unallowable *ex post facto* analysis of the present invention.

It is respectfully submitted, therefore, that the obviousness rejection previously made cannot reasonably be substantiated. The Examiner is therefore respectfully requested to withdraw the rejection.

In the event that the Examiner is motivated to deny Applicant's request and restate the obviousness rejection in different terms, the Applicant would respectfully remind the Examiner that M.P.E.P. section 2143 clearly states that to establish a *prima facie* case of obviousness, four basic criteria must be met.

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference must teach or suggest all the claim limitations. Finally, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure.

The Hill and Hall references disclose two traditional types of prior art orthoses which are very similar to those depicted in Figs. 1a, 1b, 2a and 2b of the present application.

As stated in the introduction of Applicant's specification there are two distinct forms of prior art ankle-foot orthoses - the in-shoe orthosis (as shown in Hall) and the under-shoe orthosis (as shown in Hill).

Considering first the issue of motivation, it is noted that the Hall and Hill prior art devices provide two different ways of alleviating the same medical problem. In other words, the Hall and Hill devices are actually *alternatives* to one another. A patient would either have an in-shoe device or an under-shoe device, they most certainly would not have an in-shoe device and an under-shoe device.

It follows, therefore, that a skilled person presented with Hill and Hall would immediately recognize that they are alternatives and would not be motivated to combine the references. The skilled person would appreciate that the two references disclose alternative devices.

Applicant also notes that the Hall and Hill devices would not alleviate any of the problems set out in the introduction of the application. For example, the in-shoe device (as disclosed in Hall) would be uncomfortable to walk on, and the under-shoe device (as disclosed in Hill) would immediately identify the wearer as being disabled. Neither of the devices disclosed in Hill or Hall could be worn without shoes; as someone walking on a plastic shell (as taught in Hall) would be apt to slip, and the Hill device requires the presence of a shoe to function.

It is submitted, therefore, that neither reference nor the combination of those references would help alleviate any of the problems set out in the introduction of Applicant's specification.

Applicant further notes, as explained above, that even if the two references were to be combined, they still would not disclose all of the limitations recited in independent claims 1 and 31 filed herewith. For example, they would not disclose an orthosis formed of resiliently flexible

silicone which comprised two tubular portions which were integrally formed. Furthermore, as far as amended claim 1 is concerned, neither reference discloses a first tubular portion which envelops the ankle and the entire circumference of the patient's lower leg. As far as claim 31 is concerned, neither reference discloses the provision of a second region (for example, a rib) with a second resilience greater than a first resilience, the second region augmenting the resistance to plantarflexion otherwise provided by a resiliently flexible silicone structure.

Accordingly, it is respectfully submitted that the rejection previously raised is not allowable because the Examiner has not demonstrated (a) motivation to make the combination, (b) a reasonable expectation of success, or (c) that all the claim limitations are taught or suggested by the applied art. As a consequence it is respectfully submitted that the amended claims filed herewith are patentable, and the Examiner is hereby respectfully requested to withdraw the rejection previously made.

Conclusion

In view of the above comments it is respectfully submitted that amended claims 1 and 31 are allowable over Hill or Hall considered alone or in combination.

None of the other references relied upon by the Examiner disclose or suggest the particular combination of features set out in claims 1 and 31.

The remaining claims are allowable, if only by virtue of their dependence from an allowable main claim.

It is therefore believed that all of the pending claims of this application are in condition for allowance, and early notice to that effect would be appreciated.

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231

Signed: *Sally Azevedo*
Typed Name: Sally Azevedo
Date: April 4, 2003

Respectfully submitted,

Gina McCarthy

Gina McCarthy

Reg. No. 42,986

P.O. Box 2-E

San Jose, CA 95109-0005

(408) 297-9733

Version with Markings to Show Changes Made

The sock-like structure 34 is provided with a slit 35 [(not shown)] which extends in a direction towards the calcaneum between the medial and lateral melleoli. In this embodiment, the slit is closable by a mechanical hook and loop fastener 50, such as velcro®. One portion of the fastener (ie. either a hook portion or a loop portion) is affixed to one side of the slit. The other portion of the fastener 50 is affixed to a strap 52 that is affixed to the other side of the slit.

Version with Markings to Show Changes Made

1. (amended) An ankle-foot orthosis comprising:

a first tubular portion formed of silicone;
said first tubular portion having a first end, a second end, a peripheral wall extending in a first direction from said first end to said second end, and means defining an opening in said peripheral wall;

closing means selectively operable to close said opening in said peripheral wall of said first tubular portion; and

a second tubular portion formed of silicone and having a first end and a second end, at least a portion of said first end of said second tubular portion being contiguous with at least a portion of said second end of said first portion; said second tubular portion being formed integrally with said first tubular portion to extend from said first portion in a second direction transverse to said first direction;

wherein said orthosis is arranged to be worn by a patient so that said first tubular portion envelops the patient's ankle and the entire circumference of [at least] a portion of the patient's lower leg in the vicinity of the ankle, and said second tubular portion envelops at least a portion of the plantar and dorsal aspects of the patient's foot, said first and second tubular portions being resiliently flexible to resist plantarflexion of the patient's foot.

10. (amended) An orthosis according to Claim 4, wherein the reinforcing means has a greater [stiffness] resilience than the resilience of said first and second tubular portions.

15. (amended) An orthosis according to Claim 1, wherein said second tubular portion [envelops said at least a portion of the dorsal and plantar aspects of the patient's foot without enveloping] does not envelop the patient's toes.

16. (amended) An orthosis according to Claim 1, wherein said second tubular portion [envelops said at least a portion of the plantar aspect of the patient's foot] does not [without] envelop[ing] the patient's calcaneum.

17. (amended) An orthosis according to Claim 1, wherein the [sock-like structure] first and second tubular portions [is] are of 35 shore silicone elastomer.

29. (amended) An orthosis according to Claim 2, wherein said reinforcing means comprises a first region of said peripheral wall of said first tubular structure and a second region of a peripheral wall of said second tubular structure, wherein said first and second regions are contiguous and a [thickness] resilience of said first and second tubular portion peripheral walls inside said first and second regions is greater than a [thickness] resilience of said first and second tubular portion peripheral walls outside of said first and second regions.

30. (amended) An ankle-foot orthosis according to Claim 1, wherein said [comprising:

a silicone structure having a] first tubular portion and [a] said second tubular portion [that] together define [at least a portion of] a generally L-shaped cavity[, said cavity being shaped to accept in use at least part of a patient's foot and a part of a patient's lower leg, said second portion being at least

partly contiguous with said first portion and being formed integrally therewith;

wherein the structure is of a rigidity that maintains said cavity when said orthosis is not being worn by a patient;

said first and second tubular portions are resiliently flexible to resist plantarflexion of the patient's foot; and

said first tubular portion envelops at least a portion of the patient's lower leg in the vicinity of the ankle and said second tubular portion envelops at least a portion of the plantar and dorsal aspects of the patient's foot when the orthosis is worn by the patient.]

31. (amended) An ankle foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising:

a resiliently flexible L-shaped silicone structure having a first tubular portion, and a second tubular portion that is at least partly contiguous with said first portion and is formed integrally therewith, the structure having an outer surface consisting of a first region having a first [flexural stiffness] resilience and a second region with a second [flexural stiffness] resilience that is greater than said first [flexural stiffness] resilience;

wherein said structure is configured so that said second region overlies at least a portion of a dorsal aspect of the patient's foot and a portion of the patient's lower leg when the orthosis is worn by the patient, said second region being provided to augment the resistance to plantarflexion of the patient's foot provided by the silicone structure of the orthosis.